

**REMARKS**

***I. Prompt consideration of this Amendment and Response is Respectfully Requested***

This application has been substantially delayed due to conduct of the United States Patent and Trademark Office (USPTO). The USPTO issued an Office Action with a mailing date of June 30, 2004, and the Applicant timely responded on September 30, 2004. The present Office Action has a mailing date of September 8, 2005, almost a full year after the Applicant's response. Applicant respectfully requests prompt and favorable consideration of this Amendment and Response.

***II. Amendment to the Claims***

Upon entry of the foregoing amendment, claims 17-27, 31-32, 43-44, and 55 are pending in the application, and claims 17-20, and 55 are amended. Of the pending claims, claims 17, 18, 19, 20, and 55 are independent.

***III. Claim Rejections under 35 U.S.C. § 112***

The Examiner has rejected claims 17-27, 31-32, 43-44, and 55 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

A lack of enablement rejection under section 112, Paragraph 1 is appropriate when the written description fails to teach those in the art to make and use the invention as broadly as it is claimed without undue experimentation. *See In re Vaeck*, 947 F.2d 488, 495-96, 10 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991). The first paragraph of 35 U.S.C. Section 112 requires that the specification of a patent contain a written description of the claimed invention and the manner and process of making and using that invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which that invention pertains, or with which it is most

nearly connected, to make and use that invention. *See In re Wright*, 999 F.2d 1557, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993).

A rejection under section 112, Paragraph 1 rejection can take several forms. First, the USPTO may make a scope of enablement rejection where the written description enables something within the scope of the claims, but the claims are not limited to that scope. *See In re Cortright*, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). This type of rejection is marked by language stating that the specification does not enable one of ordinary skill to use the invention commensurate with the scope of the claims. *See id.* Second, the USPTO may make a general enablement rejection, stating that the specification does not teach how to make or use the invention, if the written description does not enable any subject matter within the scope of the claims. *See id.* Here, Applicant understands the Examiner to say that although something in the claims is enabled, the scope of the claims is not commensurate with the written description.

The Examiner bears the burden of providing a prima facie case to support the rejection of a patent application. As stated by the Federal Circuit in *In re Oetiker*, “[i]f the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). Accordingly, the Examiner has the burden of showing that the application is non-enabling (i.e., that it does not teach how to make and how to use the invention). As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the

description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

*In re Wright*, 999 F.2d 1557, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993).

For the reasons set forth below, the Examiner has not established a prima facie case of non-enablement in the present Office Action.

A rejection under section 112, first paragraph requires a two-stage inquiry. *See* MPEP 2164.08. The first stage is to determine how broad the claim is with respect to the disclosure. *See id.* The second stage is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. *See id.*

A first step is to construe the claim to determine what precisely is the claimed invention. This is because when the first paragraph speaks of “the invention,” it can only be referring to that invention which the applicant wishes to have protected by the patent grant, i.e., the *claimed* invention. *See In re Moore and Janoski*, 169 U.S.P.Q. 236, 238 (CCPA 1971)(emphasis added). Put another way, the “invention” that must be enabled is that defined by the particular claim or claims of the patent or patent application. *See Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 6 U.S.P.Q.2d 1065 (D. Del. 1987), *aff’d*, 865 F.2d 1247, 9 U.S.P.Q.2d 1461 (Fed. Cir. 1989). Moreover, the level of disclosure necessary to satisfy section 112 varies according to the scope of the claimed invention. *See Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 59 U.S.P.Q.2d 1238, 1244 (Fed. Cir. 2001); *In re Wands*, 8 U.S.P.Q.2d 1400, 1402 (Fed. Cir. 1988). For these reasons, the claims must be analyzed first in order to determine exactly what subject matter they encompass. *See In re Moore*, 169 U.S.P.Q. at 238; *AK Steel Corp. v. Sollac*, 344

F.3d 1234, 1244, 68 U.S.P.Q.2d 1280, 1287 (Fed. Cir. 2003)(Because a patent specification must enable the full scope of a claimed invention, . . . an enablement inquiry typically begins with a construction of the claims); *see also* MPEP 2164.08 ([T]he first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims).

Once having determined that the subject matter defined by the claims is particular and definite, the analysis then turns to the first paragraph of section 112 to determine whether the scope of protection sought is supported and justified by the specification disclosure. *See In re Moore*, 169 U.S.P.Q. at 238. This inquiry turns upon whether that disclosure contains sufficient teaching regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and to use the claimed invention. *See id.*

In this case, the Examiner has ignored the first step, *i.e.*, claim construction, and has jumped headlong into the second stage. When the claims at issue are given their proper construction, the pending claims are enabled such that one of ordinary skill in the art could make and use the claimed invention.

Here, the Examiner has not construed the claims. Instead, the Examiner has assumed that all of the claims are directed to “the prevention of all types of headache . . .” Page 2 of Office Action. This is simply not the case. The application includes independent claims 17, 18, 19, 20, and 55. As the title of the application implies and as each independent claim recites, the claimed invention is directed toward the prevention of a headache phase of a *migraine* and not headaches in general. Thus, a first step of claim construction would be to recognize that the claims are directed to a specific type of headache.

Next, the Examiner assumes without analysis that the claims are directed to the prevention of any type of headache, regardless of cause. This interpretation of the claims is simply unreasonable. The Examiner must give claims their broadest reasonable interpretation, and this interpretation must be consistent with the one that those skilled in the art would reach. *See In re Morris*, 127 F.3d 1048, 44 U.S.P.Q.2d 1023, 1027 (Fed. Cir. 1997) (“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art . . . .”); M.P.E.P. Section 2111.01 (“[T]he words of a claim . . . must be read as they would be interpreted by those of ordinary skill in the art.”). In this case, one of ordinary skill in the art would understand that the claims are directed to the treatment of primary migraine disorders. It is simply illogical to reason that one of ordinary skill in the art would use the claimed invention for treatment of secondary migraine disorders, wherein the headache is merely a symptom of another pathological process.

The Federal Circuit has found it useful to look at references available at the time the invention was made to construe the claims in an enablement analysis. *See, e.g., In re Cortright*, 49 U.S.P.Q.2d at 1466. Here, Applicant previously submitted as part of his information disclosure statement submitted on April 17, 2001 Chapter 6 of the book Treating the Headache Patient (Roger K. Cady and Anthony W. Fox eds. 1995). Chapter 6 is entitled “Diagnosis of Headache” and is written by the Applicant, Roger Cady. As is explained in Chapter 6, primary headache disorders are those in which headache is the medical condition, whereas secondary

headache disorders are those in which headache is a symptom of another pathological process.

*See id.*; *see also* Declaration of Roger Cady (“Cady Decl.”), Par. 3.

For obvious reasons, medical personnel always seek to diagnose and treat the root cause of a medical condition. Cady Decl., Par. 4. In the context of migraines, medical personnel diagnose whether the migraine is a primary or secondary headache disorder. *Id.* If the migraine is a primary headache disorder, the medical personnel treat the migraine. *Id.* However, if the migraine is a secondary headache disorder, the medical personnel conduct further examination to identify the root cause of the headache. *Id.* The present invention is directed to primary headache disorders. *Id.*

One can also look to U.S. Patent Nos. 6,060,499 and 6,585,458. Of interest here, every claim of each patent is directed toward the treatment of migraines. The term “migraine” has a specific meaning in the field of art, and every claim of U.S. Patent Nos. 6,060,499 and 6,585,458 includes the limitation of the term “migraine.” To interpret the claims of U.S. Patent Nos. 6,060,499 and 6,585,458 as directed toward the treatment of headaches in general would be simply unreasonable. Similarly, in the present case, a broad, sweeping construction of the claims as being directed toward the treatment of headaches in general is simply unreasonable.

When the claims are interpreted in light of the specification, one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. The claims include the limitations of determining prodromal symptoms of migraine and administering an anti-migraine medication. Applicant has fully described how to determine prodromal symptoms of migraine and how to administer the anti-migraine medication.

Applicant has also provided numerous examples of anti-migraine medication. Therefore, one skilled in the art is enabled to make and use the entire scope of the properly construed claimed invention without undue experimentation.

For all of these reasons, the Examiner has failed to establish a prima facie case of non-enablement.

Even though the claims as previously presented were enabled by the specification, Applicant has amended the claims to clarify the scope of the claimed invention. Because the claims as clarified cannot be misconstrued to treat any type of headache regardless of cause, the claims as amended are plainly enabled by the specification.

Claims 17-27, 31-32, 43-44 have been amended to clarify that the claimed composition and methods are directed toward preventing the headache phase of a primary migraine disorder. Claims directed to this invention are clearly enabled by the specification. In other words, one skilled in the art could make and use the entire scope of the claimed invention without undue experimentation

Claim 55 has been amended to recite “A preemptive prophylaxis migraine method for reducing occurrence of the headache phase of a primary migraine disorder in a human . . .” The Office Action specifies on page 2 that the “specification is only enabled for a method of reducing occurrence of headache or treating headache . . .” Applicant understands this phrase to mean the *claims* for a method of reducing occurrence of headache or treating headache are enabled by the specification. As the Office Action acknowledges that this claim as amended is enabled, Applicant respectfully requests withdrawal of the section 112 rejection with respect to claim 55.

For all of these reasons, Applicant respectfully requests withdrawal of the rejection of claims 17-27, 31-32, 43-44, and 55 under 35 U.S.C. 112, first paragraph.

***IV. Claim Rejections under 35 U.S.C. § 102(e)***

The Examiner has rejected Claims 17-19, 31-32, and 43-44 as being anticipated under 35 U.S.C. §102(e) by U.S. Patent Nos. 6060499 and 6,585,458 ('499 and '458 Patents), both of which are issued to Plachetka. We note that this rejection is identical to that provided in the Office Action of June 30, 2004. Although Applicant responded to the Examiner's arguments in his September 30, 2004 Response, the present Office Action does not comment on the Response. Therefore, Applicant resubmits his prior remarks explaining why the '499 and '458 patents do not anticipate the claimed invention.

Applicant traverses the 102(e) rejection because the '499 and '458 patents do not teach every element of the claimed invention.

The Office Action alleges that the '458 patent teaches a treatment of migraine relief during the "aura" phase of a migraine. The Office Action further states, "[i]t is noted that the aura is a typical prodromal symptom of migraine . . ." These statements are not entirely correct.

As noted on pages 1, line 28 through page 2, line 2 of Applicant's Specification:

Migraine sufferers sometimes get a warning signal before the onset of the headache phase of a migraine. The warning signals apparent to the migraineur are classified as aura. The period of aura is preceded by a period classified as prodromal or premonitory period. The periods of aura, prodrome and premonitory are pre-headache.

(Emphasis added.) Several items are important to note. First, "aura" and "prodrome" are time periods, or phases, a migraineur experiences prior to a headache. These phases are not symptoms



in themselves. Second, the “prodrome” phase occurs before the “aura” phase. For obvious reasons, a migraineur would prefer to identify the onset of a migraine as early as possible.

To anticipate, the reference must teach each and every element of the claimed invention. As for independent claim 17, the cited references do not teach the combination of “determining *prodromal* symptoms” and “administering a migraine headache phase-preventing amount of 5HT agonist.” Similarly, claim 18 provides “a 5HT1 agonist as active ingredient for administration during the *prodrome* phase of migraine,” which is not taught by the references. Finally, the cited references do not teach “determining *prodromal* symptoms of migraine; and administering an anti-migraine medication” as provided in claim 19. Because the cited references do not teach each and every element of independent claims 17-19, the cited references cannot anticipate these claims. It is respectfully requested that this claim rejection be withdrawn.

#### ***V. Conclusion***


Applicant respectfully submits that the independent claims are allowable over the prior art of record, including the cited references. For similar reasons, and for the additional reasons set forth above, Applicant urge that the dependent claims are also allowable.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

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Atty. Dkt. No.: 57294-012

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

  
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